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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,706	TAI ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-7* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/05, 11/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed on June 21, 2010 to the restriction requirement of January 21, 2010 has been received. Applicant has elected with traverse Group I, claims 1-12 and 16-19, and the species of (a) assay system comprising a PSMC2 polypeptide, (b) screening assay; (C) method not further comprising steps (d) or (e)-(g), for examination. Because Applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)). Claims 1-25 are pending. Claims 13-15 and 20-25 have been withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 8-12 and 16-19 are withdrawn as being drawn to non-elected species. The species of assay system have been rejoined for examination purposes. Claims 1-7 are currently under prosecution as drawn to the elected species of assay system comprising a PSMC2 polypeptide and method not further comprising steps (d) or (e)-(g).

Claim Objections

2. Claim 4 is objected to because of the following informalities: Claim 4 recites "candidate test agent" and depends from claim 1. Claim 1 recites both a "candidate RB pathway modulating agent" and a "test agent" but no "candidate test agent," therefore, it is believed Applicants intended to recite "test agent" and NOT "candidate test agent" in claim 4. Appropriate correction is required.

3. Claim 3 is free of the art but is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,831,099, Crews et al, filed May 2000; as evidenced by Tanahashi et al (J Biological Chemistry, 2000, 275; p. 14336-14345).

Crews et al teach the 20S proteasome has chymotrypsin-like activity, trypsin-like activity, and peptidylglutamyl peptide hydrolyzing activity, and the 20S proteasome plays an important role in cell growth regulation, and apoptosis (col. 1, line 56 to col. 2, line 7).

Crews et al teach a method in Example 8 comprising the steps of:

(a) providing an assay system comprising HUVEC cells;

(b) contacting the assay system with test agents epoxomicin or lactacystin (a small molecule modulator); and

(c) detecting a difference in the activity of the assay system (i.e., levels of intracellular ubiquinated proteins and p53 levels) in the presence or absence of the test agent (col. 31, lines 5-22; col. 2, lines 8-25).

In Example 8 Crews et al teach incubation of HeLa cells with or without test agent epoxomicin and detecting a difference in the activity of the assay system (i.e., levels of intracellular ubiquinated proteins) (col. 31, lines 22-30; Figure 5).

In Examples 12 and 13 Crews et al teach:

(a) providing an assay system comprising bovine aortic endothelial (BAE) cells;

(b) contacting the assay system with test agent proteasome inhibitors; and

(c) detecting a difference in the activity of the assay system (i.e., cell proliferation, chymotrypsin-like activity, and peptidylglutamyl peptide hydrolyzing activity) in the presence or absence of the test agent (col. 37, lines 1 to col. 38, line 32; Tables 5 and 6).

Given the method taught by Crews et al detects a difference in the activity of the assay system in the presence or absence of the test agent, Crews et al necessarily identifies the test agent as a candidate RB pathway modulating agent.

As evidenced by Tanahashi et al, eukaryotic cells, including HeLa, contain 26S proteasome which comprises 20S proteasome, which inherently comprises subunit C2 (abstract; the 20S proteasome is detected by anti-C2 antibodies: p. 14337, col. 2,

second paragraph; Figure 1), hence, the assay systems taught in the method of Crews et al inherently express C2 (PSMC2) and comprise C2 polypeptide.

5. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (J Biological Chemistry, 1996, 271:32538-32545), as evidenced by Tanahashi et al (J Biological Chemistry, 2000, 275; p. 14336-14345).

Hoffman et al teach a method comprising:

(a) providing an assay system comprising 26S proteasome isolated from rabbits;

(b) contacting the assay system with test agent inhibitors of proteolysis including small molecule modulators (i.e., ouabain); and

(c) detecting a difference in the activity of the assay system (i.e., ATPase activity, ATP hydrolysis) in the presence or absence of the test agent (abstract; p. 32539, col. 1-2; p. 32541, Figure 3; Table II; p. 32542, col. 2).

Hoffman et al teach 26S proteasome of eukaryotic cells contains 20S proteasome (p. 32538, col. 1-2), and as evidenced by Tanahashi et al, the 20S proteasome inherently comprises subunit C2 (abstract; the 20S proteasome is detected by anti-C2 antibodies: p. 14337, col. 2, second paragraph; Figure 1), hence, the assay system taught in the method of Hoffman et al inherently comprises C2 polypeptide.

6. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kania et al (Eur. J. Biochemistry, 1996, 236, 510-516).

Kania et al teach a method comprising:

(a) providing an assay system comprising 20S proteasome isolated from rabbits;

(b) contacting the assay system with test agent antibodies that bind C2 (i.e., mAb GD6 and MCP20); and

(c) detecting a difference in the activity of the assay system (i.e., peptide hydrolysis; trypsin-like and eptidylglutamyl peptide hydrolyzing activity) in the presence or absence of the test agent.

Kania et al teach that the 20S proteasome is the core of a larger proteolytic complex 26S proteasome (p. 510, col. 1) and the antibodies used as test agents in the assay bind C2, wherein antibody GD6 bound C2 and inhibited proteasome activity (p. 514, col. 1), hence the assay system taught by Kania et al inherently comprises a C2 (PMSC2) polypeptide.

7. **Conclusion:** Claims 3 and 4 are objected to. Claims 1, 2, 4-7 are rejected.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642